

REMARKS

Pending claims

Claims 27, 28, and 56 are canceled herein without prejudice. Claims 63-71 are added and claims 1-4, 7, 8, 10, 11,13, 15,20, 23, 24, 25, 29, 31, 32, 39-41, 45, 47-50, 53, 54, 55 and 57-62 are amended. Upon entry of this amendment and response, claims 1-26, 29-55, and 57-80 are presented for examination. Support for the amendments and newly added claims is found throughout the specification and at least in the claims as originally filed. No new matter is added by this amendment.

Oath/Declaration

The Examiner has stated that the oath or declaration is defective because it comprises non-initialed and/or non-dated alterations and does not identify the mailing or post-office address of each inventor.

Applicants are in the process of preparing a supplemental declaration and will provide to the Examiner as soon as possible.

Claim Objections

Claims 27-60 are objected to as being improperly multiply dependent. The above amendments to the claims are made to remove improper claim dependency. Applicants respectfully submit the objection is now moot and should be reconsidered and withdrawn.

Claims 1-19, 21 and 23-26 Are Rejected Under 35 U.S.C. § 101

Claims 1-19, 21 and 23-26 are rejected for failing to recite non-statutory subject matter. The Examiner asserts that the claims read on a product of nature (i.e., a lung or simply the lung surfactant within the lung). Applicants have amended the claims to recite that the composition is "isolated", i.e., not part of a patient's body. Accordingly, Applicants submit that the rejection is now moot and respectfully requests that it be reconsidered and withdrawn.

Claims 3-4, 7-8, 11, 13-15, 20, 22 and 25 Are Rejected Under 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected the claims on a number of grounds asserting that the claims fail to particularly point out and claim the invention. Applicants respectfully submit that the rejections are now moot in view of the amendments provided herewith and respectfully request that the rejection be reconsidered and withdrawn.

Claims 1-11 and 13-26 Are Rejected Under 35 U.S.C. § 103

Claims 1-11 and 13-26 are rejected under 35 U.S.C. § 103 as being obvious over U.S. Patent No. 6,129,934 by Egan, et al. ("Egan") in view of Takahashi, et al., Acta Paediatr. Jpn 36(6): 613-8, 1994 ("Takahashi"). The Examiner asserts that Egan generally discloses lung surfactant compositions including those which comprise DPPC and surfactant apoproteins B and C and additionally discloses adding phospholipids to such compositions. The Examiner states that Egan teaches drying the surface active ingredient comprising phospholipid materials and resuspending the dried material in sterile saline. The Examiner also states that the reference teaches using the final product to treat respiratory deficiencies. The Examiner does acknowledge that Egan's compositions "lack the specific properties as claimed instantly in claims 1-2." However, the Examiner asserts that Takahashi remedies this deficiency by the reference's disclosure that the surface activity of artificial lung surfactants is improved by the addition of SP-B and SP-C. The Examiner asserts that these results suggest that a surfactant which contains SP-B and SP-C do not have to be dry or crystalline

for an effective exogenous surfactant. The Examiner states that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition of Egan et al., by adjusting the amounts of SP-B and SP-C to obtain a lung surfactant composition with desired biophysical properties as taught by Takahashi, et al.

Applicants respectfully traverse the rejection. None of the references, alone or in combination, disclose an isolated lung surfactant composition which when dispersed as a powder or as particles in an electrolyte solution is capable of forming in the course of swelling a birefringent network of tubules at an air-liquid-solid interface as observed by polarizing microscopy. Since neither Egan nor Takahashi recognized the benefits of providing lung surfactant compositions comprising ingredients which in combination have the swelling properties recited in the claims, neither reference alone, or in combination, would lead one of skill in the art to modify the Egan and/or Takahashi compositions to achieve the compositions as claimed herein.

To the extent that the Examiner appears to be arguing that the claim limitations are inherent in the compositions taught by Egan, Applicants remind the Examiner that "[i]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993). See, MPEP 2112.


Accordingly, Applicants respectfully submit that the rejection is improper and requests that the rejection be reconsidered and withdrawn.

CONCLUSION

Applicants submit that the claims are allowable and that the Application is now in condition for allowance. Applicants respectfully request early favorable action by the Examiner. If the Examiner believes that a telephone conversation with Applicants' attorney would expedite prosecution of this application, the Examiner is cordially invited to call the undersigned attorney of record.

Respectfully submitted,

Date: Sept 29, 2003



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